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10/802,166	03/17/2004	James Robert Schwartz	9184M	4150

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EXAMINER

ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/21/07 has been entered.

Claims 2, 5 and 6 have been cancelled. Claims 1, 3, 4 and 7-25 are pending.

Withdrawn rejections:

Claims 1, 4, 7-8, 12-17 were rejected under 35 U.S.C. 102(b) as being anticipated by Cilley et al. (4,933,101). Applicant has amended claim 1 to include pyrithione, which the reference of Cilley et al. does not teach. The Examiner withdraws the rejection.

Claims 14-17 were rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151). Applicant has argued that zinc carbonate is known as ZnCO_3 by one of ordinary skill in the art and not $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2$ which is basic zinc carbonate and only commercial sources refer to basic zinc carbonate as zinc carbonate (See instant specification page 6, lines 3-8). The Examiner is withdrawing the rejection with respect to claims 14-17 because Gavin et al. do not disclose the source of the zinc carbonate.

Claims 1-4, 7-17, 19-21 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wiese (US 5,227,156) in view of Blank et al. (5,883,085). Applicant has argued that zinc carbonate is known as ZnCO_3 by one of ordinary skill in the art and not $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2$ which is basic zinc carbonate and only commercial sources refer to basic zinc carbonate as zinc carbonate (See instant specification page 6, lines 3-8). The Examiner is withdrawing the rejection in favor of the rejections below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 is dependent on cancelled claim 6. The Examiner does not know from which claim 7 is dependent and is therefore indefinite. Claim 8 is rejected as being indefinite because it is dependent on an indefinite base claim. The Examiner will examine the claims as if claim 7 was dependent on claim 1 until Applicant corrects the claim dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 7-13, and 18-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151) as evidenced by the Mineral Willemite.

The Examiner sought guidance from the specification on the definition of a zinc-containing layered material. Applicant defines a zinc-containing layered material (Page 5, lines 11-16) as:

Many ZLM's occur naturally as minerals. Common examples include hydrozincite (zinc carbonate hydroxide), basic zinc carbonate, aurichalcite (zinc copper carbonate hydroxide), rosasite (copper zinc carbonate hydroxide) and many related minerals that are zinc-containing. Natural ZLM's can also occur wherein anionic layer species such as clay-type minerals (e.g., phyllosilicates) contain ion-exchanged zinc gallery ions. All of these natural materials can also be obtained synthetically or formed in situ in a composition or during a production process.

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt and an anionic deterative surfactant for a topical carrier thus reading on instant claims 1-3, 7 and 8 (Claim 1). The zinc salt can be zinc silicate, which is also known as the mineral willemite (Claim 6). Since Applicant teaches that a non-limited list of natural minerals containing zinc can also be obtained synthetically or formed in situ and Gavin et al. disclose zinc silicate, which has the same common formula for the mineral Willemite, then the zinc silicate of Gavin et al. would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than

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about 25% and thus meet the limitations of instant claims 1, 12 and 13. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11 (Page 7, lines 7-9). The concentration of the anionic surfactant ranges from about 5% to about 50% by weight of the composition consequently reading on instant claim 4 (Page 8, lines 10-16). The addition of cationic deposition polymers (instant claim 18) is anticipated (Page 20, lines 30-34-page 25, line 30). The addition of conditioning agents (instant claim 19) is anticipated (Page 35, line 12- page 47, line 16). Suspending or thickening agents are anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence anticipating instant claims 23-25 (Claim 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4 and 7-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwai et al. (EP 1145707A1) in view of Gavin et al. (WO 01/00151).

Applicant claims a composition comprising a zinc-containing layered material, a surfactant and pyrithione and methods of treating microbial infections and dandruff.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Gavin et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Iwai et al. teach compositions for external use comprising: 0.01-20 wt% of a zinc compound, such as basic zinc carbonate; 0.01-20 wt% of a thiol compound; and an anionic surfactant (Claims 1, 2, 4, 6 and 7 and page 8 lines 4 and 46 bridging page 9 line 9, for example). It is the Examiner's position that the basic zinc carbonate taught by Iwai et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Iwai et al. teach adding cationic surfactants (page 9, lines 4-9). Iwai et al. teach adding thickeners (suspending agents) such as gelatin, guar gum and methyl cellulose (page 9, lines 55-58). Iwai et al. teach the addition of various oils (conditioning agents) to the composition (page 8, lines 5-45).

Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)

1. Iwai et al. do not expressly teach a composition wherein the thiol compound is pyrithione.
2. Iwai et al. do not expressly teach a composition wherein the surfactant is present from about 2 % to about 50 %.
3. Iwai et al. do not expressly teach a composition wherein the pH is greater than about 6.5; wherein the pH is from about 6.8 to about 9.5 or the narrow range of 6.8 to about 8.5.
4. Iwai et al. do not expressly teach a method of treating microbial infections, fungal infections or dandruff with the composition.

Finding of prima facie obviousness
Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add zinc pyrithione, as suggested by Gavin et al., to the composition of Iwai et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwai et al. suggest adding thiol compounds to the composition but not specifically pyrithione and Gavin et al. cure this deficiency by teaching that zinc pyrithione is suitable for external compositions.

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2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add an anionic surfactant from about 2 % to about 50 %, as suggested by Gavin et al., to the composition of Iwai et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwai et al. suggest adding anionic surfactants to the composition but does not teach the amount. Gavin et al. cure this deficiency by providing the teaching on the amount of anionic surfactant to add to the composition.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition wherein the pH is greater than about 6.5; wherein the pH is from about 6.8 to about 9.5 or the narrow range of 6.8 to about 8.5 as suggested by Gavin et al., to the composition of Iwai et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwai et al. does not teach the pH of the composition and Gavin et al. cure this deficiency by providing the teaching on the pH for the composition.

4. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the composition of Iwai et al. in a method of treating microbial and fungal infections as well as dandruff, as suggested by Gavin et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwai et al. suggest the composition is useful for external use but not for those methods

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instantly claimed and Gavin et al. cure this deficiency by providing the teaching on the types of methods such a composition is useful for.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4 and 7-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al. (WO 01/00151) in view of Bhat et al. (WO 96/25913).

Applicant claims a composition comprising a zinc-containing layered material, a surfactant and pyrithione and methods of treating microbial infections and dandruff.

Determination of the scope and content of the prior art
(MPEP 2141.01)

The reference of Gavin et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Bhat et al. teach personal care product compositions comprising a surfactant and monophasic zinc hydroxycarbonate in an amount of 0.1-20 % by weight (Claims 1 and 2). The structure of the zinc compound is $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2 \cdot \text{X H}_2\text{O}$ where X varies between 0 and 4 (Page 6, lines 23-27). When X=0 then the same formula for basic zinc carbonate as disclosed by Applicant is taught (see instant specification page 6, line 6). It

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is the Examiner's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Bhat et al. teach the surfactant can be sodium lauryl sulphate, an anionic surfactant, in the amount of 2.5% (Page 12, line 10).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Gavin et al. do not expressly teach a composition wherein the zinc salt is a zinc layered material such as basic zinc carbonate.

**Finding of prima facie obviousness
Rational and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add basic zinc carbonate, as suggested by Bhat et al., to the composition of Gavin et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. broadly teach adding zinc salts, including the mineral zinc silicate, to the composition but not other zinc layered materials instantly claimed. Bhat et al. cure this deficiency by teaching that basic zinc carbonate is suitable for personal care compositions. Moreover, Bhat et al. teach the antimicrobial properties of basic zinc carbonate which would aid the topical composition of Gavin et al. for treating microbes (Abstract and claim 7).

One of ordinary skill in the art would have been motivated to do this because Iwai et al. suggest the composition is useful for external use and Gavin et al. cure this deficiency by providing the teaching on the types of methods such a composition is useful for.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

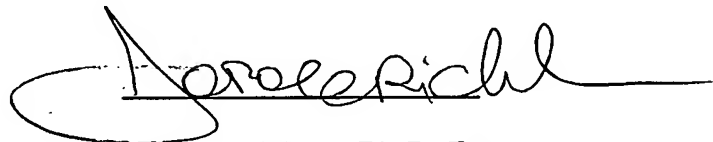
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
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A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning.

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